

**DATE:** 30 Sep 03

## **USAMMDA INFORMATION PAPER**

### **PRODUCT: TICK-BORNE ENCEPHALITIS VIRUS VACCINE**

**DESCRIPTION:** The product is an inactivated viral vaccine for prevention of Tick-borne Encephalitis (TBE). This disease is endemic in several European countries, Russia, and China. The highly pathogenic TBE virus is transmitted through the bites of ticks. After a 7-14 day incubation period, the disease is characterized by 2-4 days of low-grade fever and flu-like symptoms, followed by encephalitis in up to 30 percent of infected individuals requiring many weeks of hospitalization and rehabilitation. Mortality is 1-2 percent in general, but can be as high as 23 percent in the Far East. The TBE virus vaccine has been used in Europe for over 20 years to prevent illness due to TBE virus infection. The vaccine is licensed for use in Europe, but it is not licensed in the U.S.

**PROGRAM RELEVANCE to the ARMY:** The TBE vaccine supports the core Mission of the Army, Army Transformation, and Force Operating Capability MD 97-007 (Preventive Medicine). The TBE vaccine increases the survivability and sustainability of the force in regions of the world where TBE is endemic, thereby directly enhancing Force XXI and Objective Force operations. The TBE vaccine is key to maintaining OPTEMPO by providing protection for individual personnel, thus enabling continued operations despite the presence of endemic disease.

### **ISSUES/ACTIONS:**

- A Commercial Operations and Support Savings Initiative request for funding needed to conduct the requisite clinical trials in support of FDA licensure was denied. The clinical trial costs to support FDA licensure are prohibitive to commercial manufacturers of the TBE vaccine. Product Manager will continue to seek alternate funding sources.

**BPL#** 335

**DA PROJECT/TASK:** Infectious Diseases

PE/PROJ 643807.849TJ

**MAMP RANK:** 20/36

**ARMY ORD:** Tick-Borne Encephalitis Vaccine

Approved 9 August 1994

**CARDS #:** 1430

### **SCHEDULE:**

MS B      TBD

MS C (2-3 Yrs After MS B)

**For additional information, contact:** Pharmaceutical System Division, DSN 343-2051, Comm. 301-619-2051